K043537 pg 1/2

JAN 14 2005

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Taperloc® 12/14 Taper Femoral Components

Common Name: Total hip replacement device

Classification Names:
1) Prosthesis, hip, semi-constrained, metal/polymer, porous coated uncemented (21 CFR 888.3358)
2) Prosthesis, hip, semi-constrained, metal/polymer, porous coated, cemented (21 CFR 888.3350)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
K030055 – Expanded Indications for Non-cemented Porous Coated Total Hip Prosthesis
K921301 – Taperloc® Femoral Stem and Universal Acetabular Component
K830313 – CFE Total Hip Femoral Component – Porous Coated
K960984 – SHP Hip System
K011110 - M2a™ Acetabular System
K030047 - Freedom™ Constrained Liner

Device Description: The Taperloc® 12/14 Taper Femoral Components are straight, collarless, flat, tapered stems designed to match the geometry of the femur. The stems are proportionally sized and shaped in sizes 5.0mm to 25.0mm diameters. A lateralized version of the device is available. The stems are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F-136 or F-1472 and the proximal third of each femoral stem is covered with Biomet's full plasma spray porous coating.

Intended Use: The Taperloc® 12/14 Taper Femoral Components and M^2a-38™ Modular Heads are indicated for use in non-cemented and/or cemented total hip replacement in cases of:
1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis

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3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision of previously failed total joint replacement.

The Biomet Freedom® Constrained Modular Head is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability, and for whom all other options to constrained acetabular components have been considered.

Summary of Technologies: The overall design, materials and processing methods are similar to the predicate device

Non-Clinical Testing: Engineering analysis has demonstrated equivalence between the Taperloc® 12/14 Taper Femoral Components and the predicates.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Ms. Patricia Sandborn Beres
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46582

Re: K043537
Trade/Device Name: Taperloc® 12/14 Taper Femoral components
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: December 21, 2004
Received: December 22, 2004

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043537

Indications for Use

510(k) Number (if known): K043537

Device Name: Taperloc® 12/14 Taper Femoral Components

Indications For Use:

The Taperloc® 12/14 Taper Femoral Components and M^2a-38™ Modular Heads are indicated for use in cemented or non-cemented total hip replacement in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision of previously failed joint replacement.

The Biomet Freedom® Constrained Modular Head is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability, and for whom all other options to constrained acetabular components have been considered.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043537